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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**RHODES PHARMACEUTICALS L.P.,**

**Plaintiff,**

**v.**

**ACTAVIS, INC., ACTAVIS  
ELIZABETH LLC, ACTAVIS LLC, and  
ALLERGAN PLC,**

**Defendants.**

**Civil Action No. 16-1668 (WHW)(CLW)  
Civil Action No. 16-2667 (WHW)(CLW)**

**(Filed Electronically)**

**DISCOVERY CONFIDENTIALITY ORDER**

Pursuant to Federal Rule of Civil Procedure 26(c) and Local Civil Rule 5.3(b), Plaintiff Rhodes Pharmaceuticals L.P. ("Rhodes" or "Plaintiff") and Defendants Actavis Elizabeth LLC and Actavis LLC (collectively, "Actavis" or "Defendants") (Plaintiff and Defendants together being "the Parties"), through their respective attorneys herein, have requested that the following Discovery Confidentiality Order ("DCO") be entered to govern the exchange and use of discovery materials and testimony that the Parties regard as confidential.

The above-captioned proceeding (these "Actions") concerns a patent dispute relating to U.S. Patent Nos. 6,419,960 ("the '960 patent"), 7,083,808 ("the '808 patent"), 7,247,318 ("the

'318 patent"), 8,580,310 ("the '310 patent"), 7,438,930 ("the '930 Patent") and 9,066,869 ("the '869 patent") (collectively, "the patents-in-suit").

In light of the nature of the claims and defenses asserted by the Parties in these Actions, discovery will necessarily focus on several areas of the Parties' businesses, and potentially third-parties' businesses, deemed to be of a sensitive and proprietary nature. The areas may include, for example: (i) financial information; (ii) proprietary technology; and (iii) other sensitive business information. Testimony and documents concerning these subjects may contain confidential information, proprietary information, trade secrets, and/or other sensitive information. Because disclosure of such material may pose a substantial risk of causing harm to the Parties' competitive positions if publicly disclosed, the Parties developed and reached an agreement on a procedure for controlling disclosure of such information produced during discovery. The agreed-upon procedure is set forth in this DCO.

The nature of these Actions is such that the Parties may seek and/or produce documents and information and elicit deposition testimony, the disclosure of which may pose a substantial risk of harm to the Parties' legitimate proprietary interests. This DCO provides reasonable restrictions on the disclosure of such sensitive material. In order to streamline the discovery process and minimize the need for Court intervention, this DCO allows the Producing Party to designate certain materials being produced as "CONFIDENTIAL INFORMATION" or "HIGHLY CONFIDENTIAL INFORMATION." This DCO limits disclosure of materials designated as "CONFIDENTIAL INFORMATION" and "HIGHLY CONFIDENTIAL INFORMATION" to specific classes of persons.

This DCO also provides that the party receiving the information may challenge the Producing Party's confidentiality designation in this Court, thereby minimizing the likelihood

that non-sensitive documents will be unnecessarily designated as confidential. Each party shall act in good faith in designating information as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. Consistent with the Explanatory Note to Local Civil Rule 5.3(b), the DCO allocates to the Producing Party the burden of justifying the confidentiality designation. Orders of this type have been approved by the United States Court of Appeals for the Third Circuit. *See Pansy*, 23 F.3d at 787, n.17; *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986), *cert. denied*, 484 U.S. 976 (1987). Information and materials originally designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not retain that status after any ruling by the Court denying it such status.

Accordingly, good cause having been shown, the Court, pursuant to Fed. R. Civ. P. 26(c)(1)(G) and Local Civil Rule 5.3, hereby enters the following Order:

#### **Definitions**

1. The term “CONFIDENTIAL INFORMATION” relates to all confidential, private, product, business, commercial, or financial information and all information of a proprietary technical nature that the Designating Party believes might be of value to an actual or potential competitor of the Designating Party that is not public and that the Designating Party reasonably believes should be protected from disclosure. This includes information that the Designating Party believes, in good faith, the disclosure of which may cause harm to the competitive position of the designating party. It may include, without limitation, documents produced in these Actions, during discovery or otherwise; information of non-parties that the producing party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories, responses to requests for admission, and other discovery responses; deposition or hearing transcripts; affidavits; exhibits; experts’ reports; briefs and memoranda of law; tangible things or objects; and portions of any of the foregoing. The information contained therein and all

copies, abstracts, excerpts, summaries, analyses, notes, or other writings that contain, reflect, reveal, or otherwise disclose such confidential information shall also be deemed CONFIDENTIAL INFORMATION. Examples of such information may include without limitation:

a) information constituting, disclosing, reflecting, or relating to product discovery, design, technical and research and development information (for the products that are the subject of the litigation, and old, suspended, and abandoned projects), including, for example, preclinical and clinical development and testing or characterization information including, laboratory notebooks, development reports, testing records, research plans;

b) information constituting, disclosing, reflecting, or relating to manufacturing processes for products that are the subject of the litigation, or for products the development of which has been suspended or abandoned, including, but not limited to, active ingredient manufacturing processes and finished dosage form processes;

c) Confidential FDA filings, communications, and other confidential regulatory material, including Investigational New Drug Applications (“INDs”), New Drug Applications (“NDAs”), and Abbreviated New Drug Applications (“ANDAs”);

d) information constituting, disclosing, reflecting, or relating to third party information designated by the third party as Confidential Information.

e) Information constituting, disclosing, reflecting, or relating to business or highly sensitive commercial information including business plans, business strategies, and negotiations;

f) information constituting, disclosing, reflecting, or relating to financial information including budgeting, sales figures, accounting, and advertising expenditures

g) information constituting, disclosing, reflecting, or relating to new business development (for new and old projects);

h) information constituting, disclosing, reflecting, or relating to marketing plans;

i) information constituting, disclosing, reflecting, or relating to competitor market analysis;

j) Customer lists;

k) information constituting, disclosing, reflecting, or relating to distributor and supplier agreements and licenses;

l) Agreements with sales representatives;

m) information constituting, disclosing, reflecting, or relating to business relationships with third parties; and

n) information constituting, disclosing, reflecting, or relating to personnel information.

2. The term "HIGHLY CONFIDENTIAL INFORMATION" as used in this Order includes, and shall be limited to, CONFIDENTIAL INFORMATION that contains or is of a highly proprietary or competitively sensitive business or technical nature, or that contains trade secrets, and includes, but is not limited to, research and development directed to future products, financial, marketing, customer and commercial information, samples and non-published patent

applications.<sup>1</sup> The information contained therein and all copies, abstracts, excerpts, summaries, analyses, notes, or other writings that contain, reflect, reveal, or otherwise disclose such confidential information shall also be deemed HIGHLY CONFIDENTIAL INFORMATION.

3. The term “Protected Information” includes information that is deemed “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION.” The term “party” means any one of Rhodes or Actavis. The term “parties” shall mean Rhodes and Actavis collectively.

4. “Producing Party” shall include any producing person, entity, or third party.

5. The term “Receiving Party” shall include any receiving person or entity.

6. The term “Designating Party” shall mean the Producing Party who has designated particular materials or information as “Protected Information.”

7. The term “Qualified Person” shall mean:

a) Court and any official Court personnel involved with these Actions;

b) Outside counsel of record for the Receiving Party, who have been identified to the producing party including Counsel who have filed appearances in this litigation and their law firms’ active members, associate attorneys, paralegals, and office staffs working on this case including the secretarial, clerical, and other supporting personnel of said outside counsel (“Counsel of Record”);

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<sup>1</sup> Rhodes’ Aptensio XR, methylphenidate extended release capsules, which are the subject of New Drug Application (“NDA”) No. 205831, and Actavis’ proposed methylphenidate hydrochloride extended release capsules, which are the subject of Abbreviated New Drug Application (“ANDA”) No. 208861 are not “future products” within the meaning of this Order. For avoidance of doubt, the parties will designate NDA No. 205831 and ANDA No. 208861 as CONFIDENTIAL INFORMATION, not HIGHLY CONFIDENTIAL INFORMATION.

c) Contract attorneys retained by any party for purposes of document review and/or translation services in these Actions;

d) Any independent expert or consultant who is retained by the non-designating party's Outside Counsel (as defined above in Paragraph 7(b)) for the purpose of assisting in these Actions (and the expert or consultant's staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials), who are not past or present full-time employees of that non-designating or any other party or of an affiliate of that non-designating or any other party, provided that the provisions of Paragraph 24 below concerning advance notice are satisfied;

e) Non-technical consultants, including third party graphics or design firms, copying or imaging vendors or contractors, and information technology consultants retained by Outside Counsel (as defined above) for the Receiving Party solely for the purpose of providing litigation support, preparing demonstrative or other exhibits in connection with these Actions, including their supporting personnel;

f) Professional translators who are retained by Outside Counsel (as defined by paragraph 7(b) above) for any party for the purposes of these Actions;

g) Stenographic reporters, videographers, and official court reporters, and their assistants, who are engaged in such proceedings for the preparation and trial of these Actions;

h) Jury or trial consultants and persons employed or retained by them involved solely in providing litigation support services to any of the Parties' Outside Counsel (as defined above in Paragraph 7(b)), for purposes of these Actions, so long as

any jury or trial consultant has executed a copy of Exhibit A to this Order and agrees to be bound by the terms of this Order;

i) Any person specifically identified in an item containing or comprising HIGHLY CONFIDENTIAL material as an author or recipient of such item (or a copy thereof); and

j) Any other person who is designated as a Qualified Person by order of the Court or by written agreement of the Parties.

#### **Use of Protected Information**

8. Any information, document, or tangible thing designated as Protected Information that is disclosed and/or produced in connection with these Actions shall be maintained in strict confidence by the receiving party and shall be used solely in connection with and for the purpose of prosecuting or defending these Actions, including trial and any appeals therefrom, and shall not be disclosed to, or used by any individual or entity in any other civil actions or for any business, commercial, competitive, personal or other purpose, including, but not limited to, preparing, filing, or prosecuting any patent application, continuation, or divisional patent application, reissue patent application, or request for re-examination, or filing or defending against any *inter-parties* review or post-grant review, or any FDA communications, or any communications with the United States Pharmacopeia, or any communication with other regulatory bodies. For the avoidance of any doubt, CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION disclosed pursuant to this Order shall not be used for the purpose of counseling, litigation or other work before or involving the U.S. Food & Drug Administration ("FDA") or similar agency in a foreign country relating to methylphenidate hydrochloride. This limitation includes, but is not limited to, the preparation and filing of citizen petitions, and such work regarding any New Drug Application or Abbreviated New Drug



Application concerning methylphenidate, but excludes such work concerning, (i) updating the FDA on the status of these Actions, (ii) responding to the FDA regarding the receiving party's own NDA or ANDA, or (iii) obtaining or maintaining approval under the receiving party's own NDA or ANDA, including, but not limited to, advising the client, or responding to inquiries concerning carve-outs, exclusivities or responding to citizen petitions. Also for the avoidance of doubt, except as otherwise prohibited in paragraph 15, nothing in this paragraph 8 shall prohibit any individual from engaging in any of the proscribed activities listed in this paragraph 8 provided that such activities do not involve the use or disclosure of Protected Information.

9. It shall be the duty of each party and each individual having notice of this DCO to comply with this Order from the time of such notice. Information designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not be disclosed by the receiving party, to any individual other than those otherwise authorized to receive such information under the provisions in this document, without either the express written consent of the producing party or an order from this Court. HIGHLY CONFIDENTIAL INFORMATION shall only be relayed to, reviewed by, or stored by those individuals or entities permitted access to this information under Paragraph 14, and shall not under any circumstances be retained by, stored by, or reviewed by any employee, officer, or in-house counsel of the receiving party (including, without limitation, the specifically designated in-house personnel under Paragraph 15).

10. Nothing in this DCO shall prevent any person, including a Qualified Person, from making use of any information that is designated as Protected Information if such information:

- a) was lawfully in his or her possession prior to receipt under the provisions of this DCO;

b) was or becomes available to the public through no fault of a Receiving Party;

c) has come or hereafter comes into the Receiving Party's legitimate possession without any confidentiality restrictions and independently of the Producing Party;

d) has come or hereafter comes into the Receiving Party's legitimate possession through discovery in another legal proceeding, including any administrative proceeding before the U.S. Patent Office;

e) was or is obtained from a source not under an obligation of secrecy to the Designating Party; or

f) is exempted from the operation of this DCO by written consent of the Designating Party.

11. Nothing herein shall affect the right of the producing party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. Such disclosure shall not waive the protections of this Order and shall not entitle other parties, persons, or entities to disclose such information in violation of it, unless by such disclosure of the producing party the information becomes public knowledge. Similarly, this Order shall not preclude a party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by the opposing party.

12. If any person disputes or challenges the designation of any information as Confidential Information based on any ground, such information shall nevertheless be treated as

Protected Information in accordance with the provisions of this DCO until such designation is removed by order of the Court or by written consent of the Designating Party.

13. This DCO supersedes the Offer of Confidential Access to which the parties agreed before these Actions was filed.

**Disclosure of Protected Information**

14. Disclosure of Protected Information designated as “HIGHLY CONFIDENTIAL INFORMATION” shall be strictly limited and may be disclosed only to Qualified Persons as defined in paragraph 7 above, to the party who produced such Protected Information, and to such other persons as counsel for the Producing Party agrees in advance in writing, or as ordered by the Court.

15. Disclosure of Protected Information designated as “CONFIDENTIAL INFORMATION” shall be strictly limited in the same way as “HIGHLY CONFIDENTIAL INFORMATION” pursuant to Paragraph 14, with the exception that “CONFIDENTIAL INFORMATION” may also be disclosed to two in-house legal personnel for each side: (i) who are attorneys, and are employed by a party; (ii) who are responsible for monitoring and/or supervising this litigation; (iii) who are not responsible for competitive business decisions concerning products containing methylphenidate hydrochloride (“competitive business decisions” as used herein does not include (a) legal decision making responsibilities relating to products containing methylphenidate hydrochloride, including, for example, negotiating or executing agreements to settle litigation, including responsibilities related to any financial terms of such agreements, or advising about product launch dates, or (b) interfacing with, for the purposes of carrying out responsibilities as an attorney, individuals responsible for competitive business decisions concerning products containing methylphenidate hydrochloride); (iv) who do not participate in scientific activities for the purpose of developing products containing

methylphenidate hydrochloride (participating in “scientific activities” as used herein does not include interfacing with, for the purposes of carrying out responsibilities as an attorney, individuals responsible for scientific activities for the purpose of developing products containing methylphenidate hydrochloride); and (v) who execute a copy of Exhibit A to this Order and agree to be bound by this Order.

For Plaintiff, these in-house legal personnel shall be James P. Doyle and Christine Hlavka;

For Defendants, these in-house legal personnel shall be Rivka Jungreis;

Designated persons under this subparagraph 15 are not authorized to review or receive HIGHLY CONFIDENTIAL INFORMATION. Any person receiving HIGHLY CONFIDENTIAL INFORMATION or CONFIDENTIAL INFORMATION shall be excluded from:

a. Engaging, directly or indirectly, in any patent prosecution of any patent application that: (i) includes in its priority claim (1) an application that issued as a patent-in-suit or (2) an application included in the priority claim of any application that issued as a patent-in-suit; or (ii) includes or is amended to include claims that would be properly listable in the Orange Book in association with Aptensio XR, methylphenidate extended release capsules, in connection with NDA No. 205831. For purposes of this provision, “patent prosecution” means directly or indirectly drafting, or prosecuting new, continuing, reissue, or broadening patent claims and/or application, or materially assisting or advising with such activities. “Patent prosecution” does not include a person’s participation in litigating the scope, infringement, validity, or enforceability of any patent in any court or a person’s participation in a post-issuance proceeding before the United States Patent and Trademark Office in which the validity of any

patent is challenged (e.g., reexamination, post-grant review, and *inter partes* review), provided that persons receiving HIGHLY CONFIDENTIAL INFORMATION or CONFIDENTIAL INFORMATION may not be involved in drafting new claims or claim amendments in IPR or PGR proceedings for the Patents-in-suit or any related patent application.

b. None of the requirements in subsection (a) above are meant to exclude a representative who may have participated in such activities in the past. However, if such an individual receives HIGHLY CONFIDENTIAL INFORMATION or CONFIDENTIAL INFORMATION, such individual may not continue to participate in such activities after receipt of such information until two years after the conclusion of these Actions, including any appeal of these Actions.

16. In the event that a receiving party desires to provide access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION to any person not entitled to such access under this Order, the receiving party shall first request in writing an agreement to do so from the producing party. If the producing party refuses to enter into such an agreement within ten (10) business days, the receiving party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION after first signing a Confidentiality Agreement in the form of Exhibit A (attached hereto), a copy of which shall be forwarded promptly to counsel for the producing party, or under such other conditions as the parties to these Actions may agree or this Court may order.

17. Upon request of another party to these Actions, the Producing Party will provide to the requesting party within two (2) business days a redacted version of any pleading, brief, or expert report, that contains or refers to any Protected Information of the Producing Party, with such Protected Information redacted, so that the document may be disclosed to any in-house

individuals of the requesting party who are not Qualified Persons. In the event that the Receiving Party believes that any information redacted pursuant to this Paragraph can appropriately be disclosed to such in-house individuals, the Parties shall work together to address such concerns and bring the matter to the Court's attention if required. Notwithstanding any obligations created by this Paragraph, the process described in this Paragraph does not constitute the sole process for redacting Protected Information and does not limit in any way the rights of a Receiving Party to redact Protected Information of any party from any document, including for the purpose of disclosing a redacted version of a document to persons who are not qualified to access Confidential Information.

18. Subject to the other provisions of this DCO, Protected Information may be used, relied upon, and referred to in any testimony or other evidence presented at any trial, hearing, or deposition conducted in connection with these Actions, so long as the person presenting such testimony or evidence is authorized to have access to such Protected Information under the terms of this DCO, and subject to any further order of this Court regarding confidentiality.

19. The producing party shall have the right to exclude from portions of a deposition, before the taking of testimony which the producing party designates CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and subject to this Order, all persons other than those persons qualified to receive such information pursuant to Paragraphs 14 and 15. However, this DCO shall not limit a party's examination, at a deposition, hearing, or trial, with respect to Protected Information, of persons who are not authorized to receive Protected Information under the terms of this DCO, so long as such examination concerns Protected Information that the witness authored or previously had access to or knowledge of, as demonstrated by the Protected Information itself or by foundation testimony. This DCO shall not prevent counsel from examining a witness who was employed by the producing party during the relevant time and is reasonably believed to have had access to the CONFIDENTIAL

INFORMATION or HIGHLY CONFIDENTIAL INFORMATION in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of Protected Information.

20. Notwithstanding the foregoing, each party reserves the right to request at a hearing or trial that the courtroom be closed to the public and any non-qualified party representatives during the introduction of testimony, argument, or exhibits containing or regarding Protected Information in accordance with Local Civil Rule 5.3(c).

21. If a party intends to reveal Protected Information of another party during a trial, court appearance, hearing or other proceeding that is open to the public, the party intending to reveal such Protected Information shall provide reasonable notice and opportunity to object, unless consent from the Designating Party is previously obtained.

22. In the event that any Protected Information is used in a sealed court proceeding, it shall not lose its status through such use.

23. Nothing in this DCO shall prevent disclosure of Protected Information if the Designating Party consents to such disclosure in writing or if the Court, after notice to all parties, orders such disclosure, subject to the parties' rights to challenge any such order.

24. Disclosure of Protected Information pursuant to paragraphs 14-15 above to independent experts or consultants as defined in Subparagraph 7(d) (and to their supporting personnel) shall be made only after:

- a) Counsel desiring to disclose Protected Information to such an expert or consultant obtains a completed and signed undertaking of Confidentiality in the form of Exhibit A (attached hereto) from the expert or consultant, and forwards a copy of said completed and signed undertaking and the person's *curriculum vitae*, as well as a listing of the person's prior or current employments or consultancies for any party or



other company in the pharmaceutical industry within the last five years, and a list of the cases in which the expert or consultant has testified as an expert witness at deposition, at a hearing, or at trial in the previous four (4) years to counsel for the Producing Party; and

b) The expiration of a period of seven (7) business days, commencing with the receipt by counsel for the Producing Party of a copy of the information required by subsection (a) above. During this period, counsel for the Producing Party may object in good faith to the disclosure of Protected Information to this expert or consultant for cause, identified in writing (e.g., an identified conflict of interest). If counsel for the Producing Party fails to object to such disclosure within the prescribed period, any objection to such disclosure shall be deemed waived, except as to any basis for objection that was not known and could not have been reasonably discovered within the prescribed period. In the event that a good faith objection is made within the prescribed period, there shall be no disclosure of Protected Information to the expert or consultant until there is an express written agreement of the Parties or order of this Court resolving the dispute. Prior to seeking resolution by the Court of any disagreement as to the requested disclosure, the Parties shall meet and confer promptly and in good faith pursuant to Local Civil Rule 37.1(a)(1) in an effort to resolve such disagreement. If the Parties are unable to reach agreement over the disclosure of Protected Information to the expert or consultant, the party raising the objection shall have the obligation to seek an order of the Court preventing the disclosure and shall bear the burden of proof with respect to the propriety of its objection and blocking of said individual from serving as an expert or consultant in this case. Absent agreement between the parties to extend the deadline by which to file such a motion, any party that fails to file such a motion within ten (10)



business days of notifying a party of an objection to disclosure shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert.

c) No party will be deemed to have waived any privilege or protection from disclosure by disclosing, pursuant to Paragraph 24(a), the name of a non-testifying expert or consultant to whom counsel intends to show CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. No non-testifying expert or consultant disclosed pursuant to Paragraph 24(a) shall be subject to a deposition in connection with these Actions based solely on the fact that he or she was the subject of such disclosure. No non-testifying expert or consultant disclosed pursuant to Paragraph 24(a) shall be subpoenaed for testimony or for documents in connection with any discovery or any hearing, proceeding, or trial of these Actions based solely on the fact that he or she was the subject of such disclosure. Nothing in this paragraph is intended to limit discovery of or with regard to experts who produce reports in this case in anticipation of testifying at trial.

25. The recipient of any Protected Information shall maintain such information in a secure and safe place, and shall exercise at least the same reasonable degree of care in handling the Protected Information as is exercised by the recipient with respect to its own Protected Information of a similar nature to insure that the information and documents governed by this Order are (a) used only for the purposes specified herein, and (b) disclosed only to authorized persons as permitted by Paragraphs 14 and 15. Each recipient of any Protected Information in these Actions hereby agrees to be subject to the jurisdiction of this Court for the purpose of the implementation and enforcement of this DCO.

**Identification and Marking of Protected Information**

26. Any person or entity that is disclosing and/or producing information, documents, or tangible things may designate any such information, document, or tangible thing as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION if the producing party (a) has a good faith belief, and (b) gives notice to the receiving party (such notice may be accomplished by complying with paragraph 28 below), that such information, documents, or tangible things comprise or contain CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION within the terms of this Order and the meaning of Federal Rule of Civil Procedure 26(c). Any copies, abstracts, excerpts, summaries, analyses, notes, or other writings that contain, reflect, reveal, or otherwise disclose or are derived from such confidential information, also shall be deemed CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and the same terms regarding confidentiality of these materials shall apply as apply to the originals.

27. Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the Producing Party and a unique identifying number. Likewise, each discrete unit of any tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the Producing Party and a unique identifying number.

28. Any document or other tangible thing that contains or reveals Protected Information shall, prior to production to the receiving party, be labeled by the producing party with the legend: “**CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**” (for CONFIDENTIAL INFORMATION) or “**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY**” (for HIGHLY CONFIDENTIAL INFORMATION), or a suitable equivalent. The parties shall agree on how electronic data will be marked.. With respect to documents produced in these Actions, such markings shall appear on each page of the document

that contains such information. For pleadings and discovery responses, such marking need only appear on the first page of the document. Any document or other tangible thing so labeled and the information that it contains or reveals shall be treated in accordance with the provisions of this DCO. Any Protected Information not reduced to documentary or physical form or that cannot be conveniently labeled shall be so designated by serving a written notification on the Receiving Party.

29. When a party initially produces documents for inspection (such as for selection of materials for copying and production) that the producing party wishes to designate as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, the producing party must, prior to such disclosure for inspection or after the selection of the materials for copying and production, specify in a writing provided to the receiving party (or orally, if followed by the necessary writing) the identity of the specified information that is designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. For purposes of the inspection, all documents shall be treated as containing Protected Information if counsel for the Producing Party generally designates the class of documents as such prior to inspection.

30. Absent prior agreement of the Producing Party, only Qualified Persons, the in-house legal personnel identified under Paragraph 15, and the deponent, subject to the limitations in Paragraphs 14-15, shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.

31. At a deposition, a Producing Party may state orally on the record that portions of the deposition transcript are designated as "CONFIDENTIAL INFORMATION" or "HIGHLY CONFIDENTIAL INFORMATION." For a period of thirty (30) calendar days after receipt of

the final transcript of any deposition, the entire transcript shall be treated as CONFIDENTIAL INFORMATION. During such period, each party may review the deposition transcript and identify in writing to the other party any specific portions of pages of the deposition transcript that are to be designated “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION.” in addition to any portions that were so identified on the record during the deposition. At the expiration of the thirty-day period, any portions of the deposition transcript that were not designated as containing Protected Information either on the record during the deposition or in writing during the thirty-day period shall cease to be treated as Protected Information. Nothing in this DCO shall prevent a deponent from reviewing his or her own deposition transcript at any time.

32. If a party believes that inspection, measuring, testing, sampling, or photographing of that party’s processes, products, equipment, premises, or other property pursuant to Fed. R. Civ. P. 34 will reveal or disclose information that is in good faith deemed Protected Information, that party shall advise in advance any party or parties seeking such discovery that the inspection, measuring, testing, sampling, or photographing will be permitted only on a “Confidential Information” or “Highly Confidential Information” basis and that the material discovered, and any information derived from that material, shall be treated as Protected Information. Nothing contained in this DCO shall be deemed a waiver of any requirements for showing of good cause under the Court rules for any inspection of premises, or a waiver of any right of the Producing Party to seek an order from the Court regarding further conditions for any inspection of its premises.

33. All correspondence, legal memoranda, motion papers, pleadings, and other written materials that quote or refer to the substance of any Protected Information shall also be treated as Protected Information in accordance with the provisions of this DCO.

**Inadvertent Failure to Designate**

34. In the event that a producing party produces CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that has not been designated as such pursuant to this Order, the producing party may designate the information or documents as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION to the same extent as it may have been designated the information before production, by serving notice thereof in writing, and, where appropriate, follow by a substitute copy of each item with the appropriate designation within seven (7) business days, provided that the producing party promptly makes a good-faith representation that such production was mistaken and should have been designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. The disclosure or production of any information, document, or tangible item without the designation of such as Protected Information shall not constitute a waiver of any claim of confidentiality. Upon receiving such notification, each receiving party shall treat the designated information in accord with this Order, and each receiving party shall, within seven (7) business days after receiving such substitute copies, return to the producing party or destroy all copies of the misdesignated or non-designated information and documents. Any individuals who reviewed the information or documents prior to the notice of misdesignation or non-designation by the producing party shall honor, to the extent reasonably practicable, the provisions of this Order with respect to the use and disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION in the misdesignated or non-designated documents. No demonstration of error, inadvertence, or excusable neglect by the producing party shall be

required for designating information or documents as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION under this Paragraph.

**Inadvertent Production of Privileged or Confidential Documents**

35. Should any Protected Information be disclosed by a Receiving Party to any person not authorized to have access to such information under this DCO, the Receiving Party shall: (a) within five (5) business days of the discovery of such disclosure, inform such person of the provisions of this Order and identify such person to the Producing Party; (b) use its best efforts to obtain the prompt return of any such Protected Information and to bind such person to the terms of this Order; and (c) request such person to sign an undertaking in the form of Exhibit A. If executed, the undertaking shall be served upon counsel of record for the Producing Party within three (3) business days of its receipt by the Receiving Party. The requirements set forth in this Paragraph shall not prevent the Producing Party from applying to the Court for further or additional relief.

36. Nothing in this Order shall be construed to require disclosure of information, documents, or tangible things that counsel contends is protected from disclosure by the attorney-client privilege, the attorney work product doctrine, or any other applicable protection from disclosure. A producing party may produce a redacted version of information, documents, or tangible things that counsel contends is protected from disclosure by the attorney-client privilege, the attorney work product doctrine, or any other applicable protection from disclosure, identifying where the privileged or protected material was redacted with the designation "REDACTED" or a similar appropriate designation.

37. Pursuant to Federal Rule of Evidence 502, the inadvertent production or disclosure of any document or thing (including information) otherwise protected by the attorney-client privilege, work product immunity, or other privilege or immunity shall not operate as a

waiver of any such privilege or immunity if, after recognizing that privileged information has been produced or disclosed, the producing party who made the inadvertent production or disclosure sends to each receiving party (1) a written request for return of the inadvertently produced or disclosed document or thing within a reasonable period of time after recognizing that the privileged information has been produced or disclosed and (2) a log for the inadvertently produced or disclosed document in compliance with Federal Rule of Civil Procedure 26(b)(5)(A). The receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). Within three (3) business days of receiving such a request and log from the producing party, the receiving party shall return to the producing party all such documents and things identified by the producing party as being protected by the attorney-client privilege, work product immunity, or other privilege or immunity and as having been inadvertently produced and shall not utilize the information contained in such documents or things for any purpose. The receiving party shall also destroy all copies, abstracts, excerpts, summaries, analyses, notes, or other writings of such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information on a basis other than a waiver or estoppel premised on the inadvertent production. The producing party shall retain copies of all returned documents and tangible items for further disposition.

38. The Receiving Party may only challenge the designation of the inadvertently produced information by moving for a court order compelling production of the material. Such a motion to compel shall rely solely on the description of the inadvertently produced information that is provided in the Producing Party's log, provided that the description therein is accurate. The Receiving Party may not cite or otherwise rely on the content of the inadvertently produced



information, except that if the description in the log is inaccurate or misleading and the Producing Party refuses to correct it after consultation, the Producing Party must provide one copy of the material filed under seal with its response to the motion to compel. The Producing Party shall retain copies of all documents and tangible items subject to such a request. For purposes of this section, it shall be irrelevant which party initially discovers the inadvertently or mistakenly produced information, documents, or tangible items that are otherwise properly subject to a claim of attorney-client privilege, work product immunity, or any other applicable privilege or immunity from discovery.

### **Challenges to Protected Information Designations**

39. A Receiving Party's acceptance of material designated as Protected Information by a Producing Party shall not constitute an admission, or create an inference, that the material is in fact confidential within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G). No party shall be obligated to challenge the propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation. This DCO shall not foreclose any party from moving for an order that materials or information designated as Protected Information are not confidential within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G). Prior to bringing such a motion, however, the Receiving Party shall first request in writing that the Producing Party change or remove its confidentiality designation. If the Producing Party refuses to change its confidentiality designation within ten (10) business days, during which time counsel shall attempt to resolve their dispute on an informal basis, the Receiving Party may move for an order changing or removing the designation. On such a motion, the Producing Party shall have the burden of proving that the material or information it designated as Protected Information embodies its trade secrets or other confidential research,



development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G).

**Filing of Protected Information**

40. If the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of a producing party is to be filed with the Court in connection with these Actions, any document containing CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be filed under seal in accordance with the procedures of the United States District Court for the District of New Jersey. A party seeking to file any documents and/or things containing Protected Information shall file a motion to seal, or otherwise restrict public access to, those materials pursuant to Local Civil Rules 5.3(c) and 7.1 and in accordance with the provisions of the United States District Court for the District of New Jersey's Electronic Case Filing Policies and Procedures, as amended April 3, 2014 (the "Procedures"). All such documents so filed shall be released from confidential treatment by the Court only upon further order of the Court, subject to the rights of the parties to challenge any such order, or agreement of the Parties.

a) The burden of proving to the Court that such material designated as Protected Information should be sealed under Local Civil Rule 5.3 shall at all times remain with the Designating Party that initially designated it as Protected Information.

b) If the party filing the material is not the Designating Party, the filing party nonetheless is obligated to make a reasonable effort to meet the provisions of Local Civil Rule 5.3 to protect the Designating Party's materials. The Designating Party shall be responsible for filing supplemental motion papers pursuant to Local Civil Rule 5.3(c)(2).

41. Upon the failure of the filing or lodging party to properly designate Protected Information and file or lodge it under seal, any party or third party who in good faith believes that designation and sealing are required may move the Court to seal said information within ten (10) business days of learning of the defective filing or lodging. Notice of such motion shall be given by the moving party to all Parties in these Actions. Nothing in this provision relieves a party of liability for damages caused by failure to properly file Protected Information under seal. The burden of proving that such information should be sealed shall at all times remain on the Designating Party that initially designated it as Protected Information.

#### **Advice to Clients**

42. Nothing in this DCO shall bar or otherwise restrict an attorney from rendering advice and opinions to his or her client with respect to these Actions and, in the course thereof, referring to or relying upon his or her examination or knowledge of Protected Information; provided, however, that in rendering such advice and in otherwise communicating with his or her client, an attorney shall not disclose to any unauthorized persons any Protected Information received from another party or a third party if such disclosure would be contrary to the provisions of this DCO

#### **Discoverability of Expert Materials**

43. Where a Party retains independent consultants or experts to furnish technical or consulting services or to give testimony with respect to the patents-in-suit or the subject matter of these Actions, the following materials will be deemed to be privileged materials or materials otherwise protected from production based on a claim of privilege (attorney-client, work product or other privilege) and thus not discoverable:

- a) Correspondence between such independent consultants or experts and a party or its outside counsel;

b) Drafts of expert reports, declarations and any other materials drafted by or for such independent consultants or experts regarding the subject matter of these Actions; and

c) Communications between such independent consultants or experts and a party or its outside counsel that are related to drafts and/or revisions of expert reports, declarations, or other materials drafted by or for such independent consultants or experts, or that are related to preparation to testify at a hearing, trial, or deposition in these Actions.

Such protections provided in the preceding sentence are to be construed to be in addition to, and shall not diminish the protections provided in Fed. R. Civ. P. 26(b)(3)-26(b)(4). Nothing in this Paragraph, however, limits the rights of the Parties to examine an expert or consultant concerning the information he or she relied upon in forming his or her opinions, which information shall not be privileged.

#### **Third-Party Requests**

44. If any third party requests the production of any Protected Information, including, but not limited to, a request by subpoena, the Receiving Party in possession of such Protected Information must: (a) notify the Producing Party within seven (7) days of receiving the request; and (b) permit the Producing Party a reasonable opportunity to intervene and be heard on whether that information should be disclosed.

45. If the discovery process calls for the production of information, documents, or tangible items that a party cannot produce because its disclosure would breach an agreement with a third party to maintain such information in confidence, the producing party shall, no less than ten (10) business days after receiving the request, give written notice to the third party that its

information is subject to discovery in these Actions and provide the third party with a copy of this Order. At the same time such written notice is given to the third party, the producing party shall advise the putative receiving party of: (a) the fact that such notice has been given; (b) the type of information being withheld; and (c) the name and address of the third party. The requested information shall not be produced unless the third party so agrees or the requesting party secures a Court order compelling production.

**Miscellaneous**

46. Prior to the trial of this matter, the parties shall confer in good faith in an effort to reach agreement concerning a joint proposal to the Court with respect to the handling of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION at trial, and they shall make such proposal no later than the final pre-trial conference in these Actions. If the parties are unable to reach agreement on this subject, each party may make its own submission to the Court no later than the final pre-trial conference.

47. No party shall be responsible to another party for any use made of information that was produced and not designated as Protected Information.

48. Nothing in this DCO shall prejudice the right of any party to oppose production of any information for lack of relevance or on any other legitimate grounds.

49. Nothing in this DCO shall be construed to require disclosure of information, documents, or tangible things that counsel contends is protected from disclosure by attorney-client privilege, work product immunity, or any other applicable privilege or immunity. A Producing Party may produce a redacted version of a document, information, or tangible thing that counsel contends contains material that is protected from disclosure by attorney-client privilege, work product immunity or any other applicable privilege or immunity, identifying where such material was redacted with the designation **“Redacted-Privileged.”**

50. When preparing any privilege logs in these Actions, no party shall be required to log any documents created after February 11, 2016, i.e., the date on the face of the Paragraph IV letter sent by Actavis.

51. This Order shall be binding on any successors or assigns to any party.

52. This Order shall survive the termination of these Actions. No part of the restrictions imposed by this Order may be waived or terminated, except by specific written agreement executed by counsel of record for each producing party, or by an order of the Court for good cause shown.

53. Nothing in this DCO shall prejudice the right of any party to seek at any time a further order modifying this DCO.

54. Nothing in this DCO shall prejudice the right of any party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any Protected Information.

55. The designation of "CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION" made pursuant to this DCO shall not be construed as a concession by any party that such information is relevant or material to any issues or is otherwise discoverable.

56. Notwithstanding the foregoing provisions, this DCO shall be without prejudice to the right of any party to challenge the propriety of discovery on grounds of privilege, relevance, materiality, etc., and nothing contained herein shall be construed as a waiver of any objection that might be raised as to the admissibility at trial of any evidentiary material.

57. In the event that a new party is added, substituted, or brought in, this DCO will be binding on and inure to the benefit of the new party, along with the corresponding obligations on

the new party to maintain the confidentiality of the Protected Information, subject to the right of the new party to seek relief from or modification of this DCO.

58. Non-parties who produce information in these Actions may avail themselves of the provisions of this DCO, except that nothing in this DCO permits the disclosure of a party's Protected Information to a third party or counsel for a third party, unless by Court order, agreement of the interested parties, or as otherwise provided for in this DCO.

59. Within sixty (60) days after the termination of these Actions (including any appeals), each document and each other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be: (a) returned to the attorney of record for the Producing Party or (b) destroyed with a representation of such destruction being made to the attorney of record for the Producing Party. Notwithstanding the foregoing, Outside Counsel for a Receiving Party may retain Protected Information contained in Outside Counsel's work product, motion papers, correspondence, depositions or trial transcripts, exhibits, expert reports, discovery responses, and pleadings and materials filed with the Court — provided that counsel shall not disclose such Protected Information except as in accordance with the other provisions of this agreement.

60. The provisions of this DCO shall survive and remain in full force and effect after the termination of these Actions (including any appeals).

61. This DCO may be amended as need may arise by written agreement of the Parties, subject to court approval.

62. This DCO shall not prevent any party from applying to the Court for further or additional protective orders.

63. The United States District Court for the District of New Jersey is responsible for the interpretation and enforcement of this DCO. All disputes concerning Protected Information produced under the protection of this DCO shall be resolved by this Court.

The foregoing DCO is agreed to and accepted as to both form and substance.

**AGREED:**

Dated: October 21, 2016

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**SO ORDERED**

s/Cathy L. Waldor  
**Cathy L. Waldor, U.S.M.J.**

**Date:** 10/21/16

# EXHIBIT A



UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

RHODES PHARMACEUTICALS L.P.,

Plaintiff,

v.

ACTAVIS, INC., ACTAVIS ELIZABETH LLC,  
ACTAVIS LLC, and ALLERGAN PLC,

Defendants.

Civil Action No. 16-2667 and  
Civil Action No. 16-2667

DECLARATION AND AGREEMENT TO BE BOUND BY DISCOVERY  
CONFIDENTIALITY ORDER

I, \_\_\_\_\_ state that:

1. My home address is \_\_\_\_\_.

2. My present employer is \_\_\_\_\_ and my  
present work address is \_\_\_\_\_.

3. My present title, occupation or job description is \_\_\_\_\_.

4. A copy of my *curriculum vitae* is attached hereto.<sup>2</sup>

5. I have read and understand the provisions of the DCO entered in these Actions  
and will comply with the provisions of the DCO. I consent to be subject to the jurisdiction of  
this Court for enforcement of this DCO.

<sup>2</sup> In-house legal personnel designated under paragraph 15 and individuals defined by paragraph 7(h) of the DCO are not required to attach a *curriculum vitae*.

6. I will hold in confidence and not disclose to anyone not qualified under the DCO any CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL INFORMATION, or any summaries, abstracts or indices of any CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL INFORMATION, that is disclosed to me or that I prepare.

7. Upon conclusion of the above-captioned litigation, including any appeal(s), I will destroy or return to outside counsel for the party for whom I was employed, retained, or acted as a witness, all CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL INFORMATION – and any summaries, abstracts and indices thereof, and documents or materials that I received or prepared relating thereto – in my possession.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: \_\_\_\_\_